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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------------|
| 10/658,991 | 09/09/2003 | Ridwan Shabsigh | 0575/58075-Z/JPW/AJM/HA | 4213 |
| 7590 John P. White Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036 | | | EXAMINER KELLY, ROBERT M | |
| | | | ART UNIT 1633 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/658,991

Applicant(s)

SHABSIGH, RIDWAN

Examiner

Robert M. Kelly

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 10 and 12-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 10 and 12-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Applicant's amendment and argument of 9/13/07 are entered.

Claims 9, 14, and 18 are amended.

Claims 9, 10, and 12-21 are presently pending and considered.

Claim Rejections - 35 USC § 112 – new matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In light of the amendments, the rejections of Claims 14-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, are withdrawn.

To wit, Applicant has amended the claims to increasing VEGF levels in the penis of subjects afflicted by erectile dysfunction.

Claim Rejections - 35 USC § 112 - Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-10 and 12-21 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating erectile dysfunction, in a penis, wherein the subject is suffering from erectile dysfunction, comprising administration of a vector encoding VEGF into the corpus cavernosa, wherein the VEGF is expressed in the corpus

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cavernosa, thereby increasing or maintaining VEGF levels in the corpus cavernosa, thereby increasing or maintaining the blood supply in the corpus cavernosa, and thereby treating erectile dysfunction, does not reasonably provide enablement for the absence of expression of the VEGF, the expression of VEGF without consequent treatment of erectile dysfunction, or increasing/maintaining blood supply in the penis without treating erectile dysfunction for reasons of record, and as further expanded below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's claims encompass treating patients with erectile dysfunction, by transforming a cell of the corpora cavernosa. However, the claims do not require the expression of VEGF transgene, but only permissive conditions in the cell for expression of such. The purpose given throughout the specification for doing so is to treat erectile dysfunction, and hence, these claims must be enabled for treatment of erectile dysfunction.

The nature of the invention demonstrates that the art generally believed that new inventions in the field of gene therapy are not enabled, absent proof otherwise (e.g., Official Action of 1/13/06, pp. 9-10).

With regard to the expression of VEGF, such must necessarily be expressed, as nothing in Applicant's specification and/or the Art demonstrates that the nucleic acid alone is required to provide therapeutic effect, and the only evidence is that the VEGF protein itself provides the effect (e.g., U.S. Patent No. 6,706,682, to Shabsigh).

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Applicant's specification does not provide any more guidance or direction to reasonably predict more than is shown in the Art, and further, the Examples are limited to findings of which VEGF protein isoforms are present in the penis.

With regard to increasing/maintaining VEGF without treating erectile dysfunction (Claim 14 and dependent claims) and increasing/maintaining blood supply without treating erectile dysfunction (Claim 9 and dependent claims), it is clear that these claims are meant to embrace non-treatment methods, wherein the VEGF is too low to affect blood supply, or blood supplies not increased/maintained enough for treatment, as the claims must have a distinct scope from that of other independent claims (i.e., Claim 18). However, the whole purpose of these methods is to treat erectile dysfunction (e.g., confluence of specification, TITLE). Hence, the Artisan would have to determine what other uses exist for increasing/maintaining blood supply and increasing/maintaining blood supply in patients with erectile dysfunction, such that this specifically encompassed embodiment in each case would be enabled for something that is patentable.

Hence, the Artisan would have to experiment to determine those VEGF transgenes which could be delivered to affect therapy in normal tissues, and affect therapy without expression. Such is considered undue, as it would amount to inventing the breadth of Applicant's invention for Applicant. Still further, the Artisan would have to experiment to determine those other embodiments that are enabled which do not require treatment of erectile dysfunction (simple increases of VEGF which do not affect erectile treatment and simple increases in blood flow which do not treat erectile dysfunction). Such is also considered undue, as it would amount to inventing the breadth of specifically claimed embodiments for Applicant.

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Therefore, these claims are only enabled for such breadth as provided in the initial paragraphs of this rejection.

Response to Argument – Enablement

Applicant's argument of 9/13/07 has been fully considered but is not found persuasive.

It is noted that those arguments provided do not address the enablement with regard to expression the VEGF transgene, but the Arguments are noted to overcome the other bases of rejection argued.

With regard to the new arguments, the rejection is non-final because they could have been made before.

Claims Free of the Prior Art

The claims remain free of the prior art of record.

Conclusion

No claim is allowed.

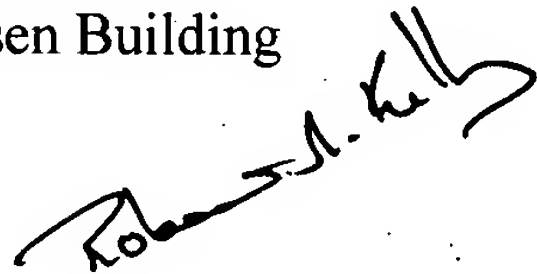
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Kelly, Ph.D.
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A handwritten signature in black ink, appearing to read "Robert M. Kelly", is written diagonally across the typed name and contact information.